

- Analyzes the policy implications of findings on health, information, outcomes, access, coverage and quality.

E.(2) Division of Aging and Disability (FKB62)

- Conducts intramural and extramural research, demonstrations and evaluations on issues that affect program eligibility for populations that include persons with mental and physical chronic disease and disabilities.

- Conducts intramural and extramural research, demonstrations and evaluations on issues that affect coverage for populations that include persons with mental and physical chronic disease and disabilities.

- Conducts intramural and extramural research, demonstrations and evaluations on issues that affect cost of care for populations that include persons with mental and physical chronic disease and disabilities.

- Conducts intramural and extramural research, demonstrations and evaluations on issues that affect access to care for populations that include persons with mental and physical chronic disease and disabilities.

- Conducts intramural and extramural research, demonstrations and evaluations on issues that affect quality of health and long-term care services for populations that include persons with mental and physical chronic disease and disabilities.

- Conducts intramural and extramural research, demonstrations and evaluations related to new measures of quality of care for populations that include persons with mental and physical chronic disease and disabilities.

- Analyzes trends in long-term care programs and market characteristics.

- Analyzes the policy implications of findings on issues that affect aging and disability.

F. Office of Research and Demonstrations Support (FKB7)

- Directs the Fiscal Intermediary and Carrier activities for demonstrations.

- Directs the development, implementation and ongoing operations of demonstrations.

- Directs the design and development of payment methodologies for demonstrations, special cost reports and operational manuals.

- Directs the design, development and implementation of mainframe and personal computer (PC) based claims processing systems and collation of evaluation data.

- Directs the development of data programs to monitor and evaluate trends

in Medicare/Medicaid and the health care system.

- Oversees programming and dataset technical assistance.

- Directs the control and support for PC's, local area networks (LAN's), computer communications and mainframe computer hardware/software packages.

- Participates with the Bureau of Data Management and Strategy (BDMS) in providing support and access to HCFA's data bases as required by research and demonstration activities.

F.(1) Division of Demonstrations Support (FKB71)

- Serves as Fiscal Intermediary and Carrier for demonstrations.

- Participates in the development, implementation and ongoing operations of demonstrations.

- Designs and develops payment methodologies when needed for demonstrations and studies, such as special cost reports, special operational manuals and participates in facilitating demonstrations.

- Designs, develops and implements mainframe and PC claims processing systems and collates data for evaluations.

- Conducts on-site audits of submitted costs reports and validates services rendered.

F.(2) Division of Data Systems Resources (FKB72)

- Develops, manages and maintains a variety of data programs to monitor and evaluate trends in Medicare/Medicaid and the health care system.

- Provides and participates in a variety of data support activities related to quality control and data verification.

- Provides programming and dataset technical assistance.

- Provides control and support for PCs, LAN, computer communications and mainframe computer hardware/software packages.

- Participates with BDMS in providing necessary support and access to HCFA's data bases as required by research and demonstration activities.

- Coordinates ORD's participation in computer-based systems.

- Designs and develops a variety of analytic data bases.

Dated: March 8, 1995.

Bruce C. Vladeck,
Administrator, Health Care Financing Administration.

[FR Doc. 95-6885 Filed 3-20-95; 8:45 am]

BILLING CODE 4120-01-P

National Institutes of Health

National Cancer Institute; Opportunity for a Cooperative Research Agreement (CRADA) for the Scientific and Commercial Development of Diagnostic and/or Therapeutic Agents for Hyperpigmentary Lesions

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI), seeks a pharmaceutical or cosmetic company that can effectively pursue the scientific and commercial generation and development of agents inhibiting pigmentation. The project is of scientific importance since it will characterize mechanisms whereby melanocyte function is compromised to produce hyperpigmented lesions. As such, this research will seek to provide insights into mechanisms responsible for clinically abnormal hyperpigmentation such as occurs in postinflammatory hyperpigmentation and other pigmentary diseases. NCI has successfully characterized the melanogenetic functions of several pigmentary genes that are important to the regulation of mammalian pigmentation. The NCI has produced a number of specific antibodies which recognize those gene products as well as a number of oligonucleotides and cDNAs whereby expression of their encoding genes can be quantitated. The selected sponsor will collaborate in a project aimed at using those probes to characterize melanocyte function in hyperpigmentary conditions and to develop agents useful commercially to down regulate melanogenic function.

ADDRESSES: Inquiries and proposals regarding this opportunity should be addressed to Mark Noel or Bert Zbar (Telephone (301) 496-0477, Facsimile (301) 402-2117), Office of Technology Development, National Cancer Institute, Bldg 31, Room 4A49, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20892

DATES: Proposals must be received at the above address by no later than May 22, 1995.

SUPPLEMENTARY INFORMATION:

"Cooperative Research and Development Agreement" or "CRADA" means the anticipated joint agreement to be entered into by NCI pursuant to the Federal Technology Transfer Act of 1986 and Executive Order 12591 of October 10, 1987 to collaborate on the specific research project described below.

The NCI is seeking a pharmaceutical or cosmetic company which can lend

resources and scientific expertise to a project aimed at identifying mechanisms responsible for abnormal melanocyte function in clinical hyperpigmentary conditions. Little is known about the level of abnormal function of melanocytes in a number of clinical conditions of hyperpigmentation, such as occurs in postinflammation, wound healing and/or photodamaged/age pigmented lesions. This proposed study will employ a number of antibodies specific for melanogenic proteins to examine melanocyte function, and thus levels of melanogenic protein expression, in such lesions. DNA probes specific for the encoding genes will be used to characterize the level of abnormal regulation of any gene products so identified. Approaches will be designed to attempt to correct abnormal expression of such genes, or the function of their encoded proteins and thus down-regulate pigmentation *in vitro*, with the ultimate goal of developing commercially useful therapeutic agents to treat conditions of epidermal hyperpigmentation. Since pigment production is inherently associated with photoprotection against UV-induced carcinogenesis, further benefit of these studies towards photoprotection may evolve. The CRADA will allow the selected partner to provide expertise and resources, in collaboration with NCI, for the preclinical development of agents useful in the treatment of epidermal hyperpigmentary conditions. Further clinical development of such agents may also be made subject to this agreement, or a separate agreement at a later date, and upon mutual agreement of the parties.

The expected duration of the CRADA will be three (3) to five (5) years.

The role of the National Cancer Institute, the Division of Cancer Biology, Diagnosis and Centers includes:

1. NCI will provide specific antibodies and probes useful to examine expression of pigmentary genes in hyperpigmented tissues.
2. NCI will perform enzymatic assays that measure melanogenic protein function in hyperpigmented tissues.
3. NCI will examine melanocyte function via expression of pigmentary genes in hyperpigmentary lesions.
4. NCI will screen potential inhibitors or down-regulators of melanogenic activity using *in vitro* techniques with melanocytes in culture.
5. NCI will collaborate with the corporate partner on the design of experiments and evaluation of results.

The role of the successful corporate partner will include:

1. Supply expertise in melanocyte function in hyperpigmentary disorders.
2. Supply potential melanogenic inhibitors or down-regulators of melanogenic activity for testing.
3. Provide funds to support a postdoctoral fellow and associated expenses of the study.
4. The corporate partner will collaborate with the NCI on the design of experiments and the evaluation of results.

Criteria for choosing the collaborating company will include:

1. Experience in the study of hyperpigmentary disorders.
2. Ability to provide adequate amounts of potential melanogenic inhibitors or down regulators of melanogenic activity for the preclinical studies which are subject to the research plan.
3. Experience and ability to produce, package, market and distribute pharmaceutical and/or cosmetic products, including experience with the regulatory approval process and with the FDA.
4. Willingness to cooperate with the NCI in the collection, evaluation, maintenance and publication of data from the investigation.
5. Willingness to share costs of the laboratory studies.
6. An agreement to be bound by DHHS rules involving the use of human and animal subjects, and human tissue.
7. Provisions for equitable distribution of patent rights to any inventions. Generally the rights of ownership are retained by the organization which is the employer of the inventor, with (1) an irrevocable, nonexclusive, royalty-free license to the Government (when a company employee is the sole inventor) or (2) an option to negotiate an exclusive or nonexclusive license to the company on terms that are appropriate (when the Government employee is the sole inventor or where a joint invention arises)

Thomas Mays,

Director, Office of Technology Development,
National Cancer Institute.

[FR Doc. 95-6855 Filed 3-20-95; 8:45 am]

BILLING CODE 4140-01-P

National Institute of Environmental Health Sciences: Opportunity for a Cooperative Research and Development Agreement (CRADA) and/or Licensing Opportunity for Preparative Two Dimensional Gel Electrophoresis System

AGENCY: National Institute of Environmental Health Sciences, National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) is seeking CRADA partners and/or licensees for the further development, evaluation, and commercialization of a Preparative Two Dimensional Gel Electrophoresis System (U.S. Patent Application Serial No. 08/243,643, filed May 16, 1994) for protein analysis and characterization. The National Institute of Environmental Health Sciences has also determined that the developed technology can be utilized in other scientific areas. The invention claimed in the above-referenced patent application is available for either further development under a CRADA and/or exclusive or non-exclusive licensing (in accordance with 35 U.S.C 207 and 37 CFR part 404) for the applications described below under **SUPPLEMENTARY INFORMATION.**

ADDRESSES: CRADA proposals and questions about this opportunity may be addressed to Dr. B. Alex Merrick, NIEHS, Mail Drop D4-03, P.O. Box 12233, Research Triangle Park, NC 27709 (Telephone: 919/541-1531; Fax: 919/541-4704; Email: MERRICK@NIEHS.NIH.GOV). CRADA proposals must be received by the date specified below.

Licensing proposals and questions about this opportunity should be addressed to: David Sadowski, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Rockville, MD 20852 (Telephone: 301/496-7735 ext. 288; Fax: 301/402-0220).

Information on the patent application and pertinent information not yet publicly described can be obtained under a Confidential Disclosure Agreement. Respondes interested in licensing the invention(s) will be required to submit an Application for License to Public Health Service Inventions. Respondes interested in submitting a CRADA proposal should be aware that it may be necessary to secure a license to the above patent rights in order to commercialize products arising from a CRADA agreement.

DATES: Capability statements/CRADA proposals must be received by NIH on or before May 22, 1995. There is no